

Translation

PATENT COOPERATION TREATY

PCT

PCT/JP2003/006679



INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Rec'd PCT/PTO 23 DEC 2004

Applicant's or agent's file reference ONF-4567PCT	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/JP2003/006679	International filing date (day/month/year) 28 May 2003 (28.05.2003)	Priority date (day/month/year) 26 June 2002 (26.06.2002)
International Patent Classification (IPC) or national classification and IPC A61K 45/00, 31/4406, A61P 3/04, 9/00, 9/04, 9/10, 11/00, 11/06, 13/08, 13/12, 17/00, 17/04, 29/00, 43/00, C07D 213/40		
Applicant ONO PHARMACEUTICAL CO., LTD.		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>	
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>	

Date of submission of the demand 06 January 2004 (06.01.2004)	Date of completion of this report 04 August 2004 (04.08.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ The international application as originally filed/furnished
- ☐ the description:
- pages _____, as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the claims:
- pages _____, as originally filed/furnished
- pages* _____, as amended (together with any statement) under Article 19
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the drawings:
- pages _____, as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
- ☒ claims Nos. 7, 1-3, 6, 8, 9 in-part

because:

- ☒ the said international application, or the said claims Nos. 7 relate to the following subject matter which does not require an international preliminary examination (*specify*):

See supplemental sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____ are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

- ☒ no international search report has been established for said claims Nos. 7, 1-3, 6, 8, 9 in-part

- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

- | | |
|----------------------------|--|
| the written form | <input type="checkbox"/> has not been furnished |
| | <input type="checkbox"/> does not comply with the standard |
| the computer readable form | <input type="checkbox"/> has not been furnished |
| | <input type="checkbox"/> does not comply with the standard |

- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

- ☐ see Supplemental Box for further details.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III.1

Claim 7 pertains to a method for the treatment of the human body by therapy, and thus relates to a subject matter for which this International Preliminary Examining Authority is not required to carry out an international preliminary examination under the provisions of PCT Article 34(4)(a)(i) and PCT Rule 67.1(iv).

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims	3, 4, 6, 9	YES
	Claims	1, 2, 5, 8	NO
Inventive step (IS)	Claims	3, 4, 6, 9	YES
	Claims	1, 2, 5, 8	NO
Industrial applicability (IA)	Claims	1-6, 8, 9	YES
	Claims		NO

2. Citations and explanations

Documents cited in the international search report:

Document 1: WO 01/60819 A1

Document 2: S. T. SVETLOV et al., Biochim. Biophys.
Acta., 23 May 2002, 1582(1-3), pages 251-256

Document 3: WO 01/71022 A2

Claims 1, 2, 5 and 8

Document 1 indicates that the compounds represented by formula [1] are LPA-receptor antagonists which are useful as therapeutic agents or prophylactic agents for cytoproliferative diseases, inflammatory diseases, renal disorders and the like. Therein, example 173 (page 112) indicates the effects of methyl 3-({4-[4-({[1-(2-chlorophenyl)ethoxy]carbonyl}amino)-3-methyl-5-isoxazoly]benzyl}sulfanyl)propanoate (which corresponds to compound (b) in the examples of the present application) in an animal model of peripheral circulatory obstructions, which are one type of chronic disorder.

Consequently, the inventions set forth in claims 1, 2, 5 and 8 lack novelty and do not involve an inventive step.

Claims 3 and 9

The documents cited in the international search report do not disclose or suggest the feature of using an EDG-2 antagonist as a therapeutic or prophylactic agent against prostatomegaly.

Claims 4 and 6

The documents cited in the international search report do not disclose or suggest a feature wherein the compounds represented by general formula (I) or general formula (III) are EDG-2 antagonists which can be used as therapeutic or prophylactic agents against chronic disorders.